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INTRODUCTION

The purpose of this multi-site study is to conduct a randomized controlled trial of the Caring Letters intervention to determine if the intervention is effective in preventing suicide and suicidal behaviors among Service Members and Veterans. The "caring letters" concept was originally developed and evaluated by Jerome Motto and colleagues in the 1970's (1). In Motto's trial, civilian psychiatric inpatients were sent caring letters following discharge (initially monthly, decreasing to quarterly) for five years. Compared to a control group (usual care) with no further contact, the Caring Letters group had a significantly lower suicide rate for the first two years of the trial. These "caring letters" are one of the only suicide prevention interventions to reduce suicide mortality in a randomized controlled trial (2). Despite the initial promising results of the original Caring Letters RCT, there have been no published replications of the original intervention or tests of the intervention among military personnel or veterans. This study will fill an important gap in the evidence base for the Caring Letter intervention and is timely given the steady increase of military suicide in recent years.

BODY

The protocol was submitted to the Madigan Healthcare System Institutional Review Board (IRB) on 07 April 2011. The Madigan IRB granted conditional approval of the research protocol on June 28, 2011. Revisions were made based on those recommendations and submitted on 07 July 2011 and the protocol was approved 22 August 2011. The protocol was reviewed by The Human Research Protection Office (HRPO) and was granted approval on November 01, 2011. An amendment was submitted to the Madigan IRB on 01 December 2011, adding T2 site personnel and additional site specific information for the other sites. This amendment was approved on 24 January 2012. The Department of Veterans Affairs (VA) IRB Palo Alto approved the protocol on 29 August 2011. The VA Western New York Buffalo (VAWNYHS) received approval on 15 November 2011. Both VA sites were reviewed and approved by HRPO on 17 February 2012. IRB documents were submitted on 13 February 2012 for the Landstuhl and Naval Medical Center San Diego (NMCSD) sites. Due to a permanent change of duty station for Dr. Wilson, a new PI for the Tripler Army Medical Center (TAMC) site was identified and IRB documents were submitted on 05 March 2012. A fully executed IAIR has been completed for TAMC as of 15 February 2012. The deferral process is continuing for Landstuhl, TAMC and NMCSD. The IAIR's for Landstuhl and NMCSD are awaiting IO signatures locally at Madigan.

A research coordinator was hired for the Madigan site at 90% effort, completed training, and began enrollment of subjects on 02 February 2012. A total of 14 subjects have been enrolled as of 28 February 2012. Interviews were conducted for a research coordinator at the Landstuhl site; an offer was made and accepted. The research coordinator will begin at 25% effort on 1 March 2012. Interviews for the coordinator position at TAMC were completed and an offer is pending. Interviews for the remaining sites are still pending selection of a candidate.

Challenges

The deferral process for TAMC, Landstuhl and NMCSD has taken longer than anticipated. A fully executed IAIR is required between Madigan and the other individual sites in order to complete the deferral process that allows Madigan to have IRB oversight. A recent change in the IO position at Madigan has delayed signatures at this site. We expect to have fully executed IAIR's with all sites within the next reporting period along with IRB approval.

KEY RESEARCH ACCOMPLISHMENTS

Administrative and Logistical Matters

1. Personnel
    a. Recruitment, interviewing and hiring a research coordinator at Madigan and Landstuhl was completed. Recruitment, interviewing and hiring a research coordinator at Palo Alto, VAWNY, TAMC, NMCSD continues.
2. Equipment
    a. None required at this time.
3. Materials, supplies and consumables
    a. Materials and required supplies continue to be coordinated in anticipation for subject enrollment and data collection.
4. Institutional Review Board (IRB)
    a. MAMC IRB approved on 28 June 2011.
    b. HRPO IRB approved on 01 November, 2011.
    c. VA Palo Alto approved on 29 August, 2011.
    d. VA Western New York Buffalo approved on 15 November 2011.
    e. HRPO IRB approved both VA sites on 17 February 2012.

REPORTABLE OUTCOMES

None

CONCLUSION

None

REFERENCES

1. Motto JA, Bostrom AG. A randomized controlled trial of postcrisis suicide prevention. *Psychiatr Serv*. 2001; 52(6):828-833.

2. Luxton, D. D., June, J. D. & Comtois, K. A. (in press). Can Post-Discharge Follow-up Contacts Prevent Suicide and Suicide Behavior?: A Review of the Evidence. *Crisis: The Journal of Crisis Intervention and Suicide Prevention.*

APPENDICIES

None